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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,616	08/06/2001	Todd J. Janus	6715.US.02	1428

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EXAMINER

COOK, REBECCA

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/923,616

Applicant(s)

JANUS ET AL.

Examiner

Rebecca Cook

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38,39,42-46,56 and 59-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38,39,42-46,56 and 59-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicants elected the claims of Group I and compound of formula III. Claims 38-39, 42-46, 56, 59-71 are being examined. All other claims have been cancelled without prejudice to their presentation in a continuation or divisional application.

Claim Rejections - 35 USC § 112

Claims 56, 59-64 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibiting bone metastases, does not reasonably provide enablement for preventing new bone metastases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The art pertaining to the treatment of cancer is still very unpredictable. While there are compounds that reduce the incidence of metastases, there are no known compounds that prevent all bone metastases.

Claims 38-39, 42-46, 56, 59-71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 38, 56 and 65 it is not clear that the metastases are metastases of prostate cancer.

There is no antecedent basis in claims 40-46, since they depend from cancelled claim 40. However, for the purpose of compact prosecution they will be examined as if they depend from claim 38.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 38-39, 42-46, 56, 59-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winn et al or 6,162,927 in view of BIOSIS AN 1999:441578 (Yin et al). Winn (abstract, Table 2) and '927 discloses that the instant compound is a known endothelin antagonist. '927 (column 2, column 264, #12, column 363, #1) discloses that the instant compounds is an endothelin antagonist and that endothelin is associated with prostate cancer. The independent claims differ over Winn and '927 in reciting inhibiting and preventing bone metastases. Dependent claims recite the additional administration of an anticancer drug, radiation or an agent that impedes net bone loss.

However, Yin (title) discloses that tumor-produced endothelin-1 mediates new bone formation via the endothelin A receptor, which leads to osteoblastic bone metastases.

It would be obvious to one of ordinary skill in the art that antagonizing endothelin with the instant endothelin antagonist would inhibit and prevent some bone metastases. That is because Yin discloses that tumor-produced endothelin-1 mediates new bone formation via the endothelin A receptor, which leads to osteoblastic bone metastases.

It would also be obvious to use anticancer drugs and radiation because the recited treatments are well-known in the cancer art and because the use of a more than

one drug and radiation is common in the cancer art. It would also be obvious to use an agent that impedes net bone loss, since they protect the bones from bone turnover that occurs during the formation of osteoblastic bone metastases.

Sarraj is considered cumulative and is no longer applied. In view of the amendments to the claims the rejection under 35 USC 103(a) over Winn in combination with WO 97/30046 (Tasker) is withdrawn.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (571) 272-0571. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Renee Jones (571) 272-0547 in Customer Service.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The official fax number is 703-872-9806

Rebecca Cook



Primary Examiner
Art Unit 1614

September 2, 2004